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10/828,653	04/20/2004	C. Randal Mills	15672US01	4918

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EXAMINER	
YOO, REGINA M	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,653	MILLS ET AL.	
	Examiner	Art Unit	
	REGINA YOO	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-74* is/are pending in the application.

4a) Of the above claim(s) *14-26 and 43-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13, 27-42 and 63-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Response to Amendment

The amendment filed on 10/14/2008 has been received and claims 1-11 and 13-74 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 27-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, there is no disclosure within the Specification that excludes use of glutaraldehyde as sterilizing agent. The disclosure pointed out by the Applicant for the support of the amendment merely points out a disadvantage but does not exclude use of glutaraldehyde just as the disclosure of disadvantage of using peroxides in the same paragraph ([04]) does not preclude use of hydrogen peroxide.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 27-30, 34-35, 39 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogle (20030229394).

As to Claims 27, 34-35 and 41, Ogle ('394) discloses a process for treating an implant so as to sterilize the implant prior to implantation (see entire document, particularly p.4 [0062]-[0063], specifically first five lines of [0063], where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response and it is deemed that use of formaldehyde for crosslinking also will sterilize the tissue as formaldehyde is a known sterilant as well as a fixative/crosslinking agent), the implant comprising a soft tissue such as a tendon or ligament (see entire document, particularly p.6 [0077]-[0078], p. 7 [0082], and p.10 [0108]), the process comprising:

applying tension to the soft tissue while contacting the soft tissue with a cleaning agent in the form of glutaraldehyde, which is a disinfecting agent and a decontaminating agent (see entire document, particularly p.10-11 paragraphs [0108]-[0113] and [0115]).

As to Claims 28-29, Ogle ('394) discloses that about 1 Newton of tension is applied to the soft tissue (see entire document, particularly p.10 [0109] and p.15 [0161] where 100 g weight provides about 1 Newton of tension).

As to Claim 30, Ogle ('394) discloses that about 3 Newtons to about 5 Newtons of tension are applied to the soft tissue (see entire document, particularly p.10 [0109]).

As to Claim 39, Ogle ('394) discloses that the process is further comprised of a step of contacting the implant with a rinsing fluid after contacting with the cleaning agent (see entire document, particularly p.11 [0118]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (20030229394) in view of Wolfinbarger (6024735).

Ogle ('394) is relied upon for disclosure described in the rejection of claim 27 under 35 U.S.C. 102(e).

As to Claim 38, Ogle ('394) does not appear to specifically teach that the process is further comprised of a step of contacting the implant with an alcohol before contact with the cleaning agent.

It was known in the art at the time of invention to provide a step of contacting an implant material with an alcohol before contacting with a cleaning agent. Wolfinbarger ('735) discloses a process of treating an implant so as to sterilize the implant prior to implantation (see entire document, particularly Abstract and Col. 1 lines 27-31) where the implant material is contacted with an alcohol (see entire document, particularly Col. 15 lines 31-35) before contacting with a cleaning agent (see entire document, particularly Col. 15 lines 54-58) in order to solubilize bone marrow and other contaminants associated with the implant material and thus to enhance the action of the cleaning solution (see entire document, particularly Col. 11 lines 24-26).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a step of contacting an implant material with an alcohol prior to contacting with a cleaning agent in the process of Ogle in order to enhance the cleaning and sterilizing process for an implant material by solubilizing the bone marrow and other associated contaminants from the implant material prior to application of the cleaning agent so that the cleaning agent will be more effective as shown by Wolfinbarger.

As to Claim 42, Ogle ('394) does not appear to specifically teach that the implant comprises a tendon having bone attached thereto.

It was well known in the art at the time of invention to provide an implant material such as a tendon having bone attached thereto. Wolfinbarger ('735) exemplifies a process for treating an implant so as to sterilize the implant prior to implantation where the implant material is a tendon having bone attached (see entire document, particularly Abstract and Col. 12 lines 50-51) in order to prepare an implant that is cleaned of blood deposits and other contaminants for use in clinical applications.

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a tendon that is attached to a bone in the process of Ogle in order to clean/sterilize and to mechanically stabilize an implant material, that will experience a load in vivo, prior to implantation as exemplified by Wolfinbarger.

Thus, Claims 38 and 42 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Ogle ('394) and Wolfinbarger ('735).

8. Claims 1-5, 7-11, 13, 27, 31-42, 63-68 and 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Ogle (20030229394).

As to Claims 1, 27, 31-35, 38-39 and 63-64, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (see entire document,

particularly Abstract), wherein the implant at least partially comprises a soft tissue (see entire document, particularly page 12, line 23), the process comprising:

(a) contacting the implant with a protective agent selected from the group consisting of alcohols and polyols (page 18, Table I Step 2 with fluid E; wherein during Step 2, alcohol is perfused into the implant – see p.18 line 20 to p.19 line 1);

(b) contacting the implant with an oxidizing sterilant (page 18, Table I Step 3 with fluid C which is hydrogen peroxide, that functions as a disinfectant and a decontaminating agent, for about 1 minute, which is less than about 80 minutes; wherein during Step 3, peroxide is perfused into the implant – see p.19 lined 2-4); and

(c) contacting the implant with a rinsing fluid (page 18, Table I Step 4; page 19, lines 9-12 with fluid such as B, which is a detergent, and/or fluid E, which is an alcohol).

Mills ('037) does not appear to specifically teach that the method is further comprised of applying tension or kinematic restraint to the soft tissue at least during part of step (b) or at least during one of steps (a), (b) or (c).

It was known in the art at the time of invention to apply tension to an implant material such as a soft tissue while performing another step such as treating/contacting the implant with a fluid to eliminate antigens and/or terminate enzymatic activity. Ogle ('394) discloses a process for making an implant more suitable for implantation into a recipient (see entire document, particularly p.4 [0062]-[0063], specifically first five lines of [0063], where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response and it is deemed that use of glutaraldehyde or formaldehyde for crosslinking also will sterilize the tissue as formaldehyde is a known sterilant as well

as a fixative/crosslinking agent), wherein the implant at least partially comprises a soft tissue (see entire document, particularly p.6 [0077]-[0078], p. 7 [0082] and p.10 [0108]), the process comprising:

applying tension to the implant/soft tissue while the implant is being contacted with a sterilant (see entire document, particularly p.10-11 paragraphs [0108]-[0112], where glutaraldehyde is a known sterilant/ disinfecting agent/decontaminating agent as well as a fixative/crosslinking agent);

contacting the implant with a rinsing fluid after contacting with the sterilant (see entire document, particularly p.11 [0118]),

in order to reduce the processing time required to separately perform the two steps so as to produce an implant that is both mechanically stabilized and that had antigens and/or enzymatic activity to eradicate hyper-acute immune response, as well to produce an implant more structurally similar to a native tissue (see entire document, particularly p.4-5 [0063] and [0065], p.10 [0108]).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide the tensioning step at least during part of step (b) in the process of Mills in order to reduce the length of processing time required to perform the tensioning step and contact with a sterilant separate and to produce a mechanically stabilized and passivated implant as shown by Ogle.

As to Claim 13, while Ogle ('394) discloses applying kinematic restraint to the soft tissue during at least part of step (b), to apply other types of fluid during the

tensioning step when the implant is not contacted with a sterilant/crosslinker (see entire document, particularly p. 8 [0092]-[0094] and p.9 [0103]-[0104]), as well as disclosing that "other processing of the tissue can be performed simultaneously with the application of a load" (see first two lines of p.11 paragraph [0115]), Ogle ('394) does not appear to specifically teach that the fluid utilized during tensioning comprises a protective agent and a rinsing fluid.

However, it would have been obvious to one of ordinary skill in this art at the time of invention to tension the implant while carrying out the other steps (i.e. steps (a) as well as step (c)) in the process of Mills during tensioning step of Ogle in order to optimize the process by utilizing these fluid contacting/treating steps both to keep the implant moist during the tensioning step as well as to process/clean/sterilize/passivate the implant at the same time, so as to reduce the overall processing time (see entire Ogle ('394) document, particularly p.8 [0092]-[0094], p.9 [0103]-[0104], p.10 [0110] and first two lines of p.11 paragraph [0115]).

As to Claims 2 and 65, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a), (b) or (c) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12).

As to Claims 3 and 66, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising:

d) contacting the implant with an oxidizing sterilant (page 19, lines 20-24; Table II); and

(e) contacting the implant with a rinsing fluid (page 20, Table II Step 4', or page 21, lines 1-3).

As to Claims 4, 40 and 67, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a) through (e) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12, or page 20, Table II Step 4' and page 21, lines 1-3).

As to Claims 5 and 68, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising the step of rinsing the implant with an aqueous solution between steps (b) and (c) (page 18, Table I Step 4).

As to Claims 7 and 70, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid is selected from the group consisting of alcohols, acetone, water, and mixtures thereof (page 18, Table I Step 4 with fluid E or mixtures; page 20, Table II Step 4' with fluid J or mixtures; page 19, lines 10-11; page 21, lines 1-2).

As to Claims 8 and 71, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid comprises a monohydric alcohol having one to eight carbon atoms (page 18, Table I Step 4 with fluid E where the alcohol is "ethanol or isopropanol" or page 20, Table II Step 4' where the fluid is J – in the form of "isopropanol, methanol").

As to Claims 9 and 72, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein step (b) comprises contacting the implant with an aqueous solution comprising hydrogen peroxide in a concentration range of from about 1% to about 10% (page 18, Table I Step 3 with fluid C where the concentration is 3% or page 20, Table II with fluid I where the concentration is 6%).

As to Claims 10, 41 and 73, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises at least one tendon or ligament (page 32, line 5).

Ogle ('394) also discloses that the implant comprising at least one tendon or ligament (see entire document, particularly p.6 [0077]-[0078] and p.10 [0108]).

As to Claims 11, 42 and 74, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises a tendon having bone attached thereto (page 31, lines 21-31).

As to Claims 36-37, Mills ('037) discloses that the cleaning agent is selected from the group consisting of alcohols (see line 8 of p.18, fluid E), a detergent (fluid B –line 5 on p.18 - for Step 3 in Table I on p.18), and mixtures and combinations thereof (see line 9 of p.18).

Thus, Claims 1-5, 7-11, 13, 27, 31-42, 63-68 and 70-74 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Mills ('037) and Ogle ('394).

9. Claims 6 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Ogle (20030229394) as applied to claims 1 and 13 above, and further in view of Wolfinbarger (6024735).

Mills ('037) and Ogle ('394) are relied upon for disclosure described in the rejection of claims 1 and 13 under 35 U.S.C. 103(a).

Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein prior to step (b) (for example during step (a)) alcohol is contacted with the implant (page 18, Table I Step 2 with fluid E).

Mills ('037) does not specifically teach that the implant contains an amount of the alcohol in the implant prior to step (b).

It was known in the art at the time of invention to contact an implant material comprising a soft tissue with alcohol where the alcohol remains within the implant prior

to contact with an oxidizing sterilant. Wolfinbarger ('735) discloses a process of treating an implant so as to sterilize the implant prior to implantation (see entire document, particularly Abstract and Col. 1 lines 27-31) where the implant material is contacted with an alcohol (see entire document, particularly Col. 15 lines 31-35) before contacting with an oxidizing sterilant (see entire document, particularly Col. 15 lines 54-58), where the alcohol remains in the implant (see Col. 15 lines 65-66), in order to further solubilize and reduce/remove bone marrow and other contaminants associated with the implant material (see entire document, particularly Col. 11 lines 24-26). It would have been obvious to one of ordinary skill in this art at the time of invention that the alcohol remains in the implant after the treatment in the process of Mills as shown by Wolfinbarger.

Thus, Claims 6 and 69 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Mills ('037), Ogle ('394) and Wolfinbarger ('735).

10. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (20030229394) in view of Wolfinbarger (6024735).

Ogle ('394) discloses a process for making an implant more suitable for implantation into a recipient (see entire document, particularly p.4 [0062]-[0063], specifically first five lines of [0063], where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response and it is deemed that use of glutaraldehyde for crosslinking also will sterilize the tissue as glutaraldehyde is a known sterilant as well as a fixative/crosslinking agent), wherein the implant at least partially

comprises a soft tissue (see entire document, particularly p.6 [0077]-[0078] and p.10 [0108]), the process comprising:

applying tension to the implant (see entire document, particularly p.10-11 paragraphs [0108]-[0112]); and

further processing the implant by perfusing the tensioned implant with a sterilizing solution such as an alcohol (see p. 10 [0118] which incorporates the US patent application No. 09/480,437, now Pat. No. 6,471,723, wherein Col. 7 lines 4-5 and Col. 10 line 6 to Col. 11 line 1, where the use of an alcohol (i.e. ethanol) is disclosed).

While Ogle ('394) teaches that other processing of the tissue can be performed simultaneously with the application of a load (see first two lines of p.11 paragraph [0115]), Ogle ('394) does not appear to specifically teach that the process is also comprised of perfusing the tensioned implant with a peroxide for less than about 80 cumulative minutes.

It was well known in the art at the time of invention to perfuse an implant with a peroxide for less than about 80 cumulative minutes. Wolfinbarger ('735) exemplifies a process for making an implant more suitable for implantation into a recipient (see entire document, particularly Abstract and Col. 1 lines 27-31), wherein the implant at least partially comprises a soft tissue, the process comprising perfusing the implant with an alcohol (see Col. 15 lines 31-35) and perfusing the implant with a peroxide for less than about 80 cumulative minutes (see Col. 15 lines 54-58 and Col. 16 lines 42-49), in order to clean the implant of bone marrow and other contaminants without altering the

properties of implant so as to reduce immunogenicity and viral load (see Col. 13 lines 1-5).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a step of perfusing the implant with a peroxide for less than about 80 cumulative minutes in the process of Ogle in order to further process the implant so that the implant is suitable for implantation in a recipient (i.e. the implant will not cause an immunogenic response).

Thus, Claim 64 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Ogle ('394) and Wolfinbarger ('735).

Response to Arguments

11. Applicant's arguments filed 10/14/2008 have been fully considered but they are not persuasive.

Specifically to Applicant's argument regarding Ogle as applied in the rejection under 35 U.S.C. 102(e), Ogle further discloses use of sterilant/fixing/crosslinking agent of formaldehyde, which is other than glutaraldehyde (see rejection above).

As to Applicant's argument that "Ogle reference does not disclose or suggest a process in which an implant comprising a soft tissue is contacted with an oxidizing sterilant…" at the bottom of page 14 and the first paragraph in page 15 of the Remarks, Examiner would point out that Applicant's arguments are against the references individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner would note that the reference of Mills teaches the limitations argued by the Applicant.

In addition, Examiner would point out that Ogle does teach applying tension to a tendon or ligament as suitable for alignment (see p. 5 [0067]-[0068] and p. 6 [0077]-[0078]), contrary to Applicant's argument that "Ogle teaches away from applying tension to a tendon or ligament suitable for alignment" in second paragraph of page 15.

Specifically, in response to applicant's argument that "claimed process yields unexpected results…[from] applying tension to tendons during the sterilization process yield tendons having improved strength as compared to non-tensioned tendons" especially regarding "the collagen degradation results set forth in Table 1" in the Specification, Examiner would agree that the results of "the collagen degradation measured for the non-tensioned implants was higher than for the tensioned implant ". However, Examiner would point out that the results provided as evidence of reduced collagen damage in Table 1 only shows the case where peroxide is used as the oxidizing sterilant and does not provide further evidence for other types of oxidizing sterilant - i.e. the evidence is not commensurate with the scope of the claims 1 and 13, in regards to Applicant's arguments in page 18.

As to Applicant's argument on page 16 that "the Zhukauskas declaration discloses that all the tendon samples were tensioned after sterilization, as a part of the test protocol for determining the tendon strength", it is noted that the post sterilization tensioning step pointed out by the Applicant was for the purpose "for evaluating tensile

strength, which included the application of a pre-defined and automated load profile, culminating in a “pull to ultimate failure load for that tendon”. In addition, it is noted that the “Tensile Hold phase of the test protocol [which] is generally intended to simulate the practice of surgeon pre-tensioning in the operating room" was applied to "both sets of tendons (those tensioned during sterilization, and those not tensioned during sterilization) as pointed out by the Applicant at the top of page 17 of Remarks. Thus, this step does not constitute a separate post-sterilization tensioning step that is applied independently from the tendon test protocols and is not deemed as such by the Examiner.

Moreover, as to Applicant’s argument in the last paragraph of page 17 to first two paragraphs on page 18 of Remarks, Examiner would continue to maintain the position that the collagen degradation results set forth in Table 1 is not persuasive because the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Examiner would take the position that as it was known in the art that applying tension separately is beneficial to the implant property, it would have been obvious and well within purview of one of ordinary skill in the art to have recognize that combining the tensioning step with application of a treating agent will produce beneficial results, such as to reduce/prevent a decrease in strength.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA YOO whose telephone number is (571)272-6690. The examiner can normally be reached on Monday-Friday, 10:00 am - 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

RY